

DETAILED ACTION

Response to Amendment

Claims 1, 2, 5-7 and 9-13 have been amended and claim 15 has been canceled as requested in the amendment filed on 12 June 2009. Following the amendment, claims 1-13, 16-21, 26, 28, 30, 34, 36, 38-41 and 44-48 are pending in the instant application.

Claims 9, 11, 13, 17-20, 26, 28, 30, 34, 36, 38, 39, 41 and 44-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03 March 2008.

Claims 1-8, 10, 12, 16, 21 and 40 are under examination in the instant office action to the extent of the elected SEQ ID NOs: 1, 28 and 35.

This application contains claims 9, 11, 13, 17-20, 26, 28, 30, 34, 36, 38, 39, 41 and 44-48 drawn to an invention nonelected with traverse in the reply filed on in the amendment filed on 12 June 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Withdrawn Claim Objections/Rejections

The objections to claims 1, 2, 5, 7 and 11 for minor informalities are withdrawn in response to the amendment of said claims correcting the informalities.

The rejection of claims 1, 2 and 16 under 35 U.S.C. 101 is withdrawn in response to the amendment of claim 1 to add "isolated."

Any previous objection to or rejection of claim 15 is hereby withdrawn as moot in response to the cancellation of said claim.

The rejection of claim 12 under 35 U.S.C. 112, second paragraph is withdrawn in response to the amendment to delete "for simultaneous, separate or sequential administration to a subject."

The rejection of claims 1, 21 and 40 under 35 U.S.C. 102(b) as being anticipated by WO 91/02078A1 to Rathjen et al. is withdrawn in response to the amendment to independent claim 1 to add that the single domain TNF antibody is a *Camelidae* variable domain.

The rejection of claims 1, 3 and 6 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,670,453 to Frenken et al. is withdrawn in response to the amendment to claim 1 to add that the single domain TNF antibody is a *Camelidae* variable domain and in response to the amendment to claim 6 to delete "corresponding to a sequence represented by".

The rejection of claims 1, 3, 4, 7, 8, 12 and 40 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,759,518 to Kontermann et al. (priority date of 09 April 1999; citation A3 on IDS dated 11 September 2006) is withdrawn in response to the amendment to independent claim 1 to add that the single domain TNF antibody is a *Camelidae* variable domain.

The rejection of claim 2 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,759,518 to Kontermann et al., in view of U.S. Patent No. 7,368,111 to Thompson et al. is withdrawn in response to the amendment of claim 2 to delete "corresponds to a sequence represented by".

The rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,759,518 to Kontermann et al., in view of U.S. Patent No. 7,084,257 to Deshpande et al. is withdrawn in response to the amendment of claim 5 to delete "correspond to a sequence represented by".

The rejection of claims 10 and 16 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,759,518 to Kontermann et al., in view of EP 584421 A1 to Casterman et al. (citation B26 on IDS dated 28 October 2008) is withdrawn in response to the amendment to independent claim 1 to add that the single domain TNF antibody is a *Camelidae* variable domain.

Any outstanding objection to or rejection of claim 15 is hereby withdrawn as moot in response to the cancellation of said claim.

New and remaining issues are set forth below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10, 12, 16, 21 and 40 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8, 44, 47 and 66 of copending Application No. 10/534,349. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '349 application are drawn to a polypeptide construct comprising: at least one single domain antibody directed against a therapeutic and/or diagnostic target, and at least one single domain antibody directed against a serum protein, (and compositions thereof), including wherein the therapeutic or diagnostic target is TNF-alpha and wherein the single domain antibodies are humanized *Camelidae* VH antibodies, as in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 10, 12, 16, 21 and 40 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

15, 22, 25-39 and 46 of copending Application No. 11/788,832. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '832 application are drawn to an anti-TNF-alpha polypeptide comprising one or more single domain antibodies directed against TNF-alpha and an Fc domain (and compositions thereof), and wherein the single domain antibodies are humanized *Camelidae* VHH antibodies, as in the instant claims. Moreover, claims 12-15 and 36-39 of the '832 application are drawn to an anti-TNF polypeptide comprising SEQ ID NO: 1, in which SEQ ID NO: 1 is identical to the instant elected sequence of SEQ ID NO: 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 10, 12, 16, 21 and 40 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10, 11, 22, 24, 25, 27 and 30-33 of copending Application No. 11/804,647. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 10 and 11 of the '647 application are drawn to a polypeptide comprising an anti-human TNF-alpha single domain antibody (dAb) and an anti-serum albumin (SA) dAb, and wherein the dAbs are Camelid VHH domains, as in the instant claims. Claims 22, 24, 25, 27 and 31-33 of the '647 application are drawn to a polypeptide comprising a first immunoglobulin single variable domain having binding specificity for serum albumin (SA), and a second immunoglobulin single variable domain having binding specificity for an antigen, including TNF-alpha, as in the instant claims. Claim

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30-33 are also drawn to a polypeptide comprising (i) first and second heavy chain single variable domains, or (ii) first and second light chain single variable domains, wherein each domain has binding specificity to an antigen including TNF-alpha, as in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In the reply filed on 12 June 2009, applicants assert that they may file terminal disclaimers when the claims are otherwise in allowable format.

Until terminal disclaimers are received and approved, the provisional obviousness-type double patenting rejections are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 16, 21 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rathjen et al. (WO 91/02078A1; Citation B5 on IDS dated 11 September 2006), in view of Els Conrath et al. (J Biol Chem 2001; Citation C6 on IDS dated 11 September 2006).

Rathjen et al. teach polypeptide ligands that bind to TNF-alpha and alter its biological activity, including single domain antibodies and polypeptides which are synthetic and analogous (i.e. homologous) to the ligands that bind to TNF (see abstract and p.4, lines 20), as in claims 1 and 16. Rathjen et al. teach a composition comprising TNF-alpha and the ligand that binds to TNF, (e.g. a TNF-alpha single domain antibody), as in claim 21. Although the patent does not explicitly recite the claimed "kit," this limitation, i.e. "a kit for screening for agents that modulate Tumor Necrosis Factor-alpha mediated disorder" is recited in the preamble of claim 21 and is thus given no patentable weight (see MPEP § 2111.02, II). The Rathjen et al. reference teaches the

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antibodies of the invention contained in pharmaceutically acceptable vehicles, e.g. phosphate buffered saline (p.19, line 25), as in claim 40. The difference between the claimed invention and that of Rathjen et al. is that Rathjen et al. do not teach that the TNF single domain antibody is a Camelidae variable domain derived from a heavy chain antibody devoid of a light chain (VHH) or a humanized Camelidae VHH, wherein the polypeptide does not include a light chain.

However, Els Conrath et al. teach that single domain antibodies against various antigens can be isolated from the heavy-chain antibodies of camels and llamas (Camilidae VHH), which do not include light chains. Although Els Conrath et al. teach selection of Camelidae antibodies from a library, the skilled artisan would have been aware that one can inoculate a camelid with a given antigen and isolate the resultant antibodies. Els Conrath et al. teach that these VHH minimal sized binders are very robust and bind the antigen with high affinity in a monomeric state and teaches that these can be used to form bivalent constructs (which thus have at least one single domain antibody; see p.7346, abstract and second full paragraph). Els Conrath et al. do not teach that the single domain antibodies are TNF single domain antibodies.

However, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify the compositions of Rathjen as taught by Els Conrath to yield predictable results. As evidenced by the Rathjen reference, the artisan of ordinary skill would have known that treatment with a TNF single domain antibody would be useful to decrease the undesirable biological activity of TNF (abstract). As evidenced by the Els Conrath reference, the artisan of ordinary skill

would have known that Camilidae VHH antibodies to a given antigen are desirable because they are minimal sized binders, which bind the antigen with high affinity in a monomeric state (see p.7346, abstract). Thus, it would have been reasonable to predict that the compositions of Rathjen could be successfully altered to provide the Camilidae VHH single domain antibodies as taught by Els Conrath et al. Therefore, the artisan of ordinary skill would have found it obvious to generate a TNF polypeptide comprising the TNF single domain antibody as claimed to yield predictable results. This is because the artisan has good reason to pursue the known options within his or her technical grasp to obtain predictable results. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense (see *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007).

Claims 1, 10, 16, 21 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rathjen et al. (WO 91/02078A1; citation B5 on IDS dated 11 September 2006), in view of EP 584421 A1 to Casterman et al. (Citation B26 on IDS dated 28 October 2008).

Rathjen et al. teach polypeptide ligands that bind to TNF-alpha and alter its biological activity, including single domain antibodies and polypeptides which are synthetic and analogous (i.e. homologous) to the ligands that bind to TNF (see abstract and p.4, lines 20), as in claims 1 and 16. Rathjen et al. teach a composition comprising TNF-alpha and the ligand that binds to TNF, (e.g. a TNF-alpha single domain antibody), as in claim 21. Although the patent does not explicitly recite the claimed "kit," this

limitation, i.e. "a kit for screening for agents that modulate Tumor Necrosis Factor-alpha mediated disorder" is recited in the preamble of claim 21 and is thus given no patentable weight (see MPEP § 2111.02, II). The Rathjen et al. reference teaches the antibodies of the invention contained in pharmaceutically acceptable vehicles, e.g. phosphate buffered saline (p.19, line 25), as in claim 40. The difference between the claimed invention and that of Rathjen et al. is that Rathjen et al. do not teach that the TNF single domain antibody is a Camelidae variable domain derived from a heavy chain antibody devoid of a light chain (VHH) or a humanized Camelidae VHH, wherein the polypeptide does not include a light chain.

However, Casterman et al. teach that heavy chain antibodies from camelids (i.e. Camelidae VHH, which comprise two heavy chain single domains and do not include light chains) are desirable because they are not associated with a pathological situation which would induce the production of abnormal antibodies with respect to the four-chain immunoglobulins. Casterman et al. teach how to prepare a camelid antibody against essentially any antigen (p. 9 lines 25-27 and 35-41). Casterman et al. teach that these antibodies can be humanized, and thus would be less immunogenic for human use (entire document, e.g. abstract, pp.2-3, p.5, lines 47-54), as in claims 1, 10 and 16. Casterman et al. do not teach that the single domain antibodies are TNF single domain antibodies.

However, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify the compositions of Rathjen as taught by Casterman to yield predictable results. As evidenced by the Rathjen

reference, the artisan of ordinary skill would have known that treatment with a TNF single domain antibody would be useful to decrease the undesirable biological activity of TNF (abstract). As evidenced by the Casterman reference, the artisan of ordinary skill would have known that Camilidae VHH antibodies to a given antigen are desirable because they are not associated with a pathological situation which would induce the production of abnormal antibodies with respect to the four-chain immunoglobulins (see p.3, lines 35-44). Thus, it would have been reasonable to predict that the compositions of Rathjen could be successfully altered to provide the humanized Camilidae VHH antibodies as taught by Casterman et al. Therefore, the artisan of ordinary skill would have found it obvious to generate a TNF polypeptide comprising TNF Camelidae VHH antibodies as claimed to yield predictable results. This is because the artisan has good reason to pursue the known options within his or her technical grasp to obtain predictable results. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense (see *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007).

Claims 3, 4, 7, 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rathjen et al. (WO 91/02078A1; citation B5 on IDS dated 11 September 2006), in view of Els Conrath et al. (J Biol Chem 2001; Citation C6 on IDS dated 11 September 2006) as applied to claims 1, 16, 21 and 40 above, and further in view of Kontermann et al. (U.S. Patent No. 6,759,518; priority date of 09 April 1999; citation A3 on IDS dated 11 September 2006).

Rathjen et al. and Els Conrath et al. teach as set forth above. The difference between the claimed invention and the disclosures of these references is that the references do not specifically teach a particular polypeptide construct with at least one single domain antibody directed against TNF-alpha and one directed against serum albumin or a particular construct with at least one single domain antibody directed against TNF-alpha and one directed against IFN-gamma.

However, the Kontermann patent teaches polypeptide constructs comprising at least one or at least two single domain antibodies with at least two specificities, including a therapeutic and/or diagnostic target (col.3, lines 31-45). The Kontermann patent teaches that therapeutic targets for the single domain antibodies can be cytokines, such as TNF-alpha and IFN-gamma (col.7, line 18; col.14, line 55) and that another specificity can be serum albumin (col.1, lines 16-20; cols 14-16, especially col.16, line 18), as in claims 3, 4, 7 and 12. The patent teaches an example of a polypeptide construct, which has 4 single domains, 2 with a first specificity and 2 with a second specificity (col.3, lines 31-45), as in the instant claim 8. The patent teaches pharmaceutical compositions comprising the polypeptides (col.9, lines 59-65), as in claim 12. The patent does not teach a polypeptide construct comprising Camelidae VHH as claimed.

However, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify the compositions of Rathjen as taught by Els Conrath and Kontermann to yield predictable results. As evidenced by the Rathjen reference, the artisan of ordinary skill would have known that treatment with a

TNF single domain antibody would be useful to decrease the undesirable biological activity of TNF (abstract). As evidenced by the Els Conrath reference, the artisan of ordinary skill would have known that Camilidae VHH antibodies to a given antigen are desirable because they are minimal sized binders, which bind the antigen with high affinity in a monomeric state (see p.7346, abstract). As evidenced by the Kontermann reference, the artisan of ordinary skill would have known multi-specific single chain antibody constructs with specificities to TNF-alpha, IFN-gamma and/or serum albumin would be desirable for treatment and/or diagnostic purposes (col.1, lines 16-20; col.3, lines 31-45; col.7, line 18; col.14, cols 14-16). Thus, it would have been reasonable to predict that the compositions of Rathjen could be successfully altered to provide the Camilidae VHH single domain antibodies as taught by Els Conrath et al. and the target specificities taught by Kontermann. Therefore, the artisan of ordinary skill would have found it obvious to generate a recombinant polypeptide as claimed to yield predictable results. This is because the artisan has good reason to pursue the known options within his or her technical grasp to obtain predictable results. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense (see *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007).

Claims 3, 4, 7, 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rathjen et al. (WO 91/02078A1; citation B5 on IDS dated 11 September 2006), in view of EP 584421 A1 to Casterman et al. (Citation B26 on IDS

dated 28 October 2008) as applied to claims 1, 10, 16, 21 and 40 above, and further in view of Kontermann et al. (U.S. Patent No. 6,759,518; priority date of 09 April 1999; citation A3 on IDS dated 11 September 2006).

Rathjen et al. and Casterman et al. teach as set forth above. The difference between the claimed invention and the disclosures of these references is that the references do not specifically teach a particular polypeptide construct with at least one single domain antibody directed against TNF-alpha and one directed against serum albumin or a particular construct with at least one single domain antibody directed against TNF-alpha and one directed against IFN-gamma.

However, the Kontermann patent teaches polypeptide constructs comprising at least one or at least two single domain antibodies with at least two specificities, including a therapeutic and/or diagnostic target (col.3, lines 31-45). The Kontermann patent teaches that therapeutic targets for the single domain antibodies can be cytokines, such as TNF-alpha and IFN-gamma (col.7, line 18; col.14, line 55) and that another specificity can be serum albumin (col.1, lines 16-20; cols 14-16, especially col.16, line 18), as in claims 3, 4, 7 and 12. The patent teaches an example of a polypeptide construct, which has 4 single domains, 2 with a first specificity and 2 with a second specificity (col.3, lines 31-45), as in the instant claim 8. The patent teaches pharmaceutical compositions comprising the polypeptides (col.9, lines 59-65), as in claim 12. The patent does not teach a polypeptide construct comprising Camelidae VHH as claimed.

However, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify the compositions of Rathjen as taught by Casterman and Kontermann to yield predictable results. As evidenced by the Rathjen reference, the artisan of ordinary skill would have known that treatment with a TNF single domain antibody would be useful to decrease the undesirable biological activity of TNF (abstract). As evidenced by the Casterman reference, the artisan of ordinary skill would have known that Camilidae VHH antibodies to a given antigen are desirable because they are not associated with a pathological situation which would induce the production of abnormal antibodies with respect to the four-chain immunoglobulins (see p.3, lines 35-44). As evidenced by the Kontermann reference, the artisan of ordinary skill would have known multi-specific single chain antibody constructs with specificities to TNF-alpha, IFN-gamma and/or serum albumin would be desirable for treatment and/or diagnostic purposes (col.1, lines 16-20; col.3, lines 31-45; col.7, line 18; col.14, cols 14-16). Thus, it would have been reasonable to predict that the compositions of Rathjen could be successfully altered to provide the humanized Camilidae VHH antibodies as taught by Casterman et al. and the target specificities taught by Kontermann. Therefore, the artisan of ordinary skill would have found it obvious to generate a recombinant polypeptide as claimed to yield predictable results. This is because the artisan has good reason to pursue the known options within his or her technical grasp to obtain predictable results. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense (see *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007)).

Conclusion

No claims are allowed.

It is noted that the art does not teach or suggest SEQ ID NO: 1, 28 and 35, and that claims to these specific sequences would be allowable.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G.E./

Gregory S. Emch
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Art Unit 1649
05 November 2009

/Daniel E. Kolker/
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November 6, 2009